



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-21-21DI]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled CryptoNet Case Report Form to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on March 8, 2021 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

CryptoNet Case Report Form - New - National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Cryptosporidium are a genus of parasites that cause the diarrheal disease cryptosporidiosis. As part of *Cryptosporidium* case and outbreak investigations, it is common for state and local health departments to conduct comprehensive interviews with cases and contacts to identify how individuals became sick with cryptosporidiosis, to identify individuals who could have come into contact with an individual sick with cryptosporidiosis, and to identify strategies to control the disease spread. Since cryptosporidiosis can be transmitted through numerous modes, it can be challenging to identify how individuals could have become ill. As a result, comprehensive case report forms focused on a range of settings, activities, and potential modes of transmission are needed to guide prevention and control activities.

The CryptoNet case report form (CRF) was developed to meet the needs of CDC's case surveillance experts and local officials. The CRF includes a set of data elements that can be used to identify exposure trends in outbreak- and non-outbreak-associated *Cryptosporidium* cases, to generate hypotheses about

the source(s) of infection in clusters or outbreaks, and to identify strategies to prevent and control *Cryptosporidium* cases, clusters, or outbreaks. CryptoNet is meant to supplement existing cryptosporidiosis case surveillance data reported through the National Notifiable Diseases Surveillance System (NNDSS) (OMB No. 0920-0728, Exp. 3/31/2024). Current cryptosporidiosis case surveillance through NNDSS lacks information on key exposures proposed to be captured by CryptoNet. Notably, information proposed to be collected as part of CryptoNet serves as the foundation for the recently developed foodborne and diarrheal diseases message mapping guide - cryptosporidiosis tab (FDD MMG). The FDD MMG is the latest revision to NNDSS that aims to increase the amount of exposure data collected on each cryptosporidiosis case. Upon nationwide implementation of the FDD MMG, NCEZID anticipates that the CryptoNet Case Report form will be retired.

Administration of the CRF is to conduct surveillance on exposures associated with *Cryptosporidium* cases to better inform prevention and control strategies for these infections. There are no research questions addressed. Standardized data will be compiled on recent exposures related to cryptosporidiosis with the intention to inform disease prevention and control activities and will not be used to inform generalizable knowledge. CDC's CryptoNet staff and the Case Surveillance node in CDC's Waterborne Disease Prevention Branch (WDPB) will oversee data collection, data management, and analyses and

dissemination of data collected with the CRF during cryptosporidiosis investigations. The data collected from the CRF will be used to inform exposure trends among cases, clusters, or outbreaks with the intention to identify and implement prevention and control strategies and recommendations.

The CRF data elements and form were designed for administration via telephone interview with cases of cryptosporidiosis or their proxies. This method was chosen to reduce the overall burden on respondents because it allows for the assessment team to ask for clarification from participants during the interview, and this limits the need for additional follow-up. The data collection instrument was designed to collect the minimum information necessary for the purposes of this project.

Based on the annual number of laboratory specimens collected by the *Cryptosporidium* laboratory at CDC, it is expected that an average of 500 CryptoNet CRFs will be collected each year. OMB approval is requested for three years. Participation is voluntary and there are no costs to respondents other than their time. The total estimated annualized burden is 125 hours.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
Individuals ill	CryptoNet	500	1	15/60

with Cryptosporidiosis, or their designated proxy	Case Report Form			
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[FR Doc. 2021-15790 Filed: 7/23/2021 8:45 am; Publication Date: 7/26/2021]